August 24, 2016

Wendy Cleland-Hamnett
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001
Sent electronically to www.regulations.gov Docket ID# EPA-HQ-2016-0399

Re: ACC Comments to Inform EPA's Rulemaking on the Prioritization of Chemicals for Further Risk Evaluation under the Lautenberg Chemical Safety Act (LCSA)

Dear Ms. Cleland-Hamnett:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide written comments to the Office of Pollution Prevention and Toxics (OPPT) to inform the Agency's development of a prioritization process rule under the Lautenberg Chemical Safety Act (LCSA). ACC is committed to being a constructive stakeholder in the effective implementation of the LCSA and we provide these comments to assist the Agency in its development of a chemical evaluation and management program that is efficient, science-based, and consistent with the legal requirements of the LCSA.

The prioritization process is the first step in the LCSA's framework for evaluating chemicals in commerce. The prioritization process rule must establish a risk-based screening process and criteria to identify high and low priority substances for risk evaluations under the LCSA. In our attached comments, ACC clarifies many of the points we raised at EPA's August 10 public stakeholder meeting on the prioritization rule. We hope these comments are helpful to the Agency in its development of the rule, as well as any necessary guidance, consistent with the LCSA's requirements.

If you have any questions, please contact me at: 202-249-6403 or Sarah_Brozena@americanchemistry.com

Sincerely,

Sarah H. Brozena

Sarah Brozena
Senior Director, Regulatory & Technical Affairs

cc: Jim Jones, OCSPP Assistant Administrator
Jeffery T. Morris, Deputy Director for Programs, OPPT
Maria Doa, Director, Chemical Control Division, OPPT

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

## EXECUTIVE SUMMARY

The prioritization process rule that EPA is required to establish under Section 6(b) of the Lautenberg Chemical Safety Act (LCSA) must address both procedural requirements and scientific process requirements. Sections 6(b)(1) and (2) and Sections 26(h), (i) and (j) of the Lautenberg Chemical Safety Act (LCSA) require EPA to address the following basic elements of a "risk based screening process" in its rule to designate substances as high or low priority for risk evaluations:

- Prioritization criteria
- Legal standard for designations
- Timeframe for designations
- EPA's request for relevant information
- Proposal of a designation and opportunity for public comment
- Final prioritization designations
- Extension of timeframe to submit information and limitation
- High priority throughput
- Low priority throughput
- Minimum number of priorities from Work Plan
- Continuing designations
- Preference criteria
- Metals
- EPA's use of information, methods, etc., in prioritization screening, consistent with best available science
- EPA's use of weight of the scientific evidence in priority designations
- Publication of information, analysis and basis for designation
- Guidance

Several other provisions in the LCSA also play an important role in EPA's implementation of the Section 6(b) prioritization provisions, including Sections 4, 8 and 14. EPA must address in its prioritization process rule how it will use its Section 4 testing authority to prioritize substances under Section 6(b). EPA's use of Section 8 reporting as a source of information for prioritization must also be addressed in the rule. Finally, EPA must address how it will utilize and continue to protect confidential information during the prioritization process, consistent with Section 14 of the LCSA.

In anticipation of EPA building from its TSCA Work Plan Methodology early in its implementation of the LCSA, the American Chemistry Council (ACC) recommends several near and long term improvements to that Methodology to identify priority substances for risk evaluations under the LCSA.

**American Chemistry Council**
**Initial Input to U.S. Environmental Protection Agency**
**In Regard to a Prioritization Process Rule under the Lautenberg Chemical Safety Act**

The American Chemistry Council (ACC) is pleased to provide the U.S. Environmental Protection Agency (EPA) its initial input on the Lautenberg Chemical Safety Act's (LCSA) requirement for the Agency to establish, by rule, a risk-based screening process to identify high and low priority substances for risk evaluations under the LCSA. ACC appreciates EPA's early efforts to obtain input from stakeholders at its August 10, 2016 public meeting. We also appreciate EPA's solicitation of written comments to be entered into the docket, well in advance of EPA's proposed rule on the prioritization process. Our comments clarify the oral comments we presented at the August 10 meeting.

ACC strongly supported Congress's efforts to update and reform the Toxic Substances Control Act (TSCA). One of ACC's principles for modernizing TSCA called on EPA to systematically prioritize chemicals for purposes of risk evaluations. Without prioritization, EPA would not be able to meet the other requirements of the LCSA in an efficient manner.

Prioritization of chemicals for various purposes is not new to the Agency. In 2012, EPA published its methodology to identify chemicals for its TSCA Work Plan for Chemical Assessment (Work Plan) program. EPA invited stakeholder input on how it should do this during its 2011 Stakeholder Dialogue on Prioritization and on EPA's Discussion Blog. In our comments to that discussion blog, ACC highlighted principles for prioritization. We believe these principles are now generally reflected in the LCSA requirements, in particular the LCSA's recognition that prioritization is a risk based screening process that integrates information on both hazard and exposure potential. In 2011, ACC developed a tool to "proof test" our prioritization principles. We presented our principles and our prioritization tool to EPA in 2011, as well as to other industry and NGO stakeholders at the time. We have provided both these documents (Attachments A and B) in these comments to assist EPA in its development of the prioritization process rule and any necessary guidance, consistent with the new requirements of the LCSA.

## I. Overview of LCSA's Prioritization Requirements under Section 6(b)(1)-(2)

Sections 6(b)(1) and (2) of the LCSA address EPA's prioritization of chemical substances for risk evaluations. Section 6(b)(1) establishes the basic requirement that EPA establish – by rule -- a "risk based screening process," including criteria for designating substances as high or low priority for risk evaluations. The language specifies what EPA must "consider" in this process and it lays out the standard by which substances will be designated as high priority or low priority.

Section 6(b)(1) also prescribes the timeframe (between 9-12 months) within which final prioritization designations must be made once EPA initiates the process; the requirement for EPA to request interested persons submit "relevant information"; the time period (90 days from initiation of the prioritization process) for persons to submit information to EPA; the requirement for EPA to propose its priority designation "along with an identification of the information, analysis, and basis" used to make the

designation; and a 90 day public comment period on the proposed designation. There is also an opportunity to extend the deadline for submitting information to EPA if that information is required under Section 4, subject to certain limitations.

The Section 6(b)(2) requirements relate to EPA's identification of the first 10 high priority substances; EPA's throughput of high and low priority designations over 3½ years and beyond; preference criteria for EPA to designate priorities from the Work Plan; and treatment of metals and metal compounds in the priority designations.

Of particular note is that this prioritization rule must establish a "risk based screening process" and EPA must publish its proposed designation along with the "information, analysis and basis" used to make that proposed designation. These requirements are significant because they relate directly to other requirements in Section 26, discussed in more detail below.

## II. The Relationship between Section 6(b)(1) and Section 26 of the LCSA

In ACC's oral statements at the August 10, 2016, stakeholder meeting on prioritization, ACC emphasized that the Agency must incorporate certain elements of LCSA Section 26 into the Section 6(b) prioritization process rule.

Section 26(h) requires EPA to use scientific information, methods, etc., consistent with the best available science, to the extent that EPA must make a decision based on science in carrying out Sections 4, 5 and 6. In addition, Section 26(i) requires EPA to make decisions under Sections 4, 5 and 6 based on the weight of the scientific evidence. Further, Section 26(j) specifically requires EPA to publish its proposed high priority and low priority designations under Section 6(b) with the information, analysis and basis used to make its proposed designation. Each of these three provisions impose specific requirements on EPA in the Section 6 prioritization process: 1) EPA must use the best available scientific information and methods to designate high and low priorities; 2) EPA must use of the weight of the scientific evidence to analyze the information and methods to designate priorities; and 3) EPA must publish the basis of its priority designations. These requirements reveal that this rule is more than simply a procedural process rule, but rather, it is a rule that must also address the substantive science based processes by which EPA will designate priorities.

It is ACC's position that because the Section 26 (h), (i) and (j) provisions are, in fact, legal requirements of the LCSA that are applicable to the prioritization process "rule" requirements, EPA must incorporate these requirements into the prioritization rule rather than solely in guidance. If Congress had intended the scientific standard of "best available science" or "weight of the scientific evidence" to be incorporated into guidance alone, it would have included them only in Section 26(l) on "policies, procedures and guidance."

It should be clear, however, that EPA can describe some of the details of its prioritization methodology and decision making process in guidance. ACC's position is that the LCSA Sections 26(h), 26(i) and 26(j) requirements must be addressed in the prioritization rule because they are mandatory and because doing so will provide the regulated community, the broader stakeholder community and EPA itself greater certainty about what EPA will rely upon when making prioritization designations. Specifically, based on Sections 26(h), (i) and (j), the prioritization rule must require EPA to: apply that scientific

information, procedures, methods, models, etc., in a manner reasonable for, consistent with, and relevant to EPA's use of it for prioritization purposes; discuss the extent to which it has evaluated and characterized the uncertainty of the information it uses to prioritize chemicals for risk evaluations; consider the extent to which the information or methods or models it uses to prioritize have been independently verified and/or validated; use a "weight of the scientific evidence" approach in making its prioritization decisions; and publish the priority designation along with the information, analysis and basis used to make the designation.

To be clear, ACC is not suggesting that EPA's application of "best available science" and "weight of the scientific evidence" under the prioritization and risk evaluation steps in Section 6 must be identical. The Section 26 requirements do not necessarily impose the same level of rigor to the scientific information and analyses that EPA might use to prioritize chemicals for risk evaluations as may be needed to conduct the risk evaluation of the high priority chemicals. ACC believes that the Section 26 requirements for best available science and weight of the scientific evidence presume that these requirements would be "fit for purpose" – i.e., the purpose of the initial screening of chemicals into high and low priority bins for the risk evaluation stage.

In summary, based on Sections 6(b)(1), 6(b)(2) and 26 (h), (i) and (j) ACC recommends that EPA include the following basic procedural and scientific process requirements in the prioritization process rule.

- **Prioritization Criteria:** EPA must define the criteria for designating high priority and low priority substances for risk evaluation (Section 6(b)(1)(A)).
- **Legal Standard:** EPA must explain its interpretation of the "may present an unreasonable risk" legal standard by which EPA will designate high and low priorities (Section 6(b)(1)(B)).
- **Timeframe for Designations:** The rulemaking must ensure that the time required to make a priority designation is no shorter than 9 months and no longer than 1 year (Section 6(b)(1)(C)).
- **EPA's request for relevant information:** Within the overall timeframe, and before EPA proposes a designation, EPA must request interested persons to submit relevant information on a substance EPA has initiated a prioritization process on. The process must provide 90 days for information to be submitted to EPA (Section 6(b)(1)(C)(i)).
- **Proposal of a designation and opportunity for public comment:** Within the overall timeframe, the process must include the requirement for EPA to propose a priority designation, including the information, analysis, and basis that EPA used to make its proposed priority designation. The process must provide 90 days for public comment on each proposed designation (Section 6(b)(1)(C)(ii)).
- **Final prioritization designations and relationship to risk evaluations:** The rule must require EPA to publish its final prioritization designations. The rule should also make clear that upon designation of substances as a high priority that EPA must initiate a risk evaluation (Section 6(3)(A).
- **Extension and limitation:** The rule must address the opportunity for extension of the 90-day deadline for submitting relevant information for up-to-three months to allow EPA to receive or evaluate information required under Section 4(a)(2)(B). The rule must also address the limitation that if information remains insufficient to designate a substance as low priority, EPA must designate it as a high priority. (Section 6(b)(1)(C)(iii)).

- **High Priority Throughput:** The rule must require that EPA ensure that within 3 and ½ years from enactment, a minimum of 20 high priorities are designated and risk evaluations on them are underway.
- **Low Priority Throughput:** The rule must include the requirement that at least 20 low priority substances be designated within 3 and ½ years from enactment.
- **Minimum Number of Priorities from Work Plan:** The rule must include the requirement that at least 50% of the 20 high priorities are drawn from the Work Plan.
- **Continuing designations:** The continuing designations of priorities must be at a pace consistent with EPA's ability to complete the risk evaluations within the Section 6(b)(4)(G) deadlines.
- **Preference Criteria:** The rule must address the preference criteria for substances from the Work Plan.
- **Metals:** The rule must specify the use of the Framework for Metals Risk Assessment or its successor document, etc., in identifying the priorities of metals and metal compounds.
- **Consistent with the "best available science" requirement,** the rule must describe the type, relevance and quality of the information the Agency will rely upon in prioritization of substances for risk evaluation.
- **Consistent with the "best available science" requirement**, the rule must describe the degree of rigor in the methods, models, etc., that EPA will rely upon to prioritize substances for risk evaluation.
- **Consistent with the "best available science" requirement,** the rule must include a placeholder (when ready for prioritization purposes) for applying advanced 21st century methodologies to prioritize chemicals based on both hazard and exposure potential, e.g., ToxCast and Omics testing methods and QIVIVE for hazard potential; and high throughput exposure modeling for exposure prediction.
- **Weight of the Scientific Evidence:** The rule must include the elements of the weight of the scientific evidence framework EPA will use to prioritize substances for risk evaluations.
- **Publication of Information, Analysis and Basis for Designation:** The rule must describe the process by which the Agency will meet its Section 26(j) and Section 6(b)(1)(C)(ii) requirements to develop and publish the information, analysis and basis for its proposed designations.
- **Guidance:** The rule must include a reference to the necessary Section 26(l) guidance that EPA must develop to provide additional detail and explanation of its expectations for the type and quality of information and methods, etc. that it will use to designate priorities for risk evaluations under the law.

## III. Relationship between Section 6 Prioritization Requirements and Section 4 testing

When making prioritization designations, EPA should use all available relevant and reliable data and information about a substance (e.g., physical chemical properties, hazard potential, exposure potential) to meet the best available science requirements discussed earlier in these comments. EPA can and should rely upon read-across, modeling, and structural-activity relationships when making prioritization designations. EPA can and should rely on relevant and available modeled and measured exposure information (often the key to prioritization). Numerous screening-level exposure models and frameworks exist which can even be iterated to accommodate additional higher tier information such as actual human and environmental data. For certain substances, biomonitoring data can give information on actual

human exposure, which when combined with biomonitoring equivalents[1] can provide powerful risk-based information useful for prioritization.

However, there may be circumstances in which there is insufficient information and/or an inability to rely upon certain information to establish the priority of a substance. In those cases, the LCSA provides EPA authority to use Section 4 to seek relevant data and information. EPA can employ its Section 4 authority either before or after it initiates the prioritization process – but "only if" EPA determines the information is "necessary to establish the priority of the substance," subject to the limitation that 90 days after receipt of the information, EPA must designate it as a high or low priority. In addition, the information "shall not be required for purposes of establishing or implementing a minimum information requirement of broader applicability."

If EPA employs its Section 4 authority for a specific substance after it initiates the prioritization process, ACC believes the Agency has discretion to remove the specific substance from the prioritization process pending receipt of the information developed under Section 4. There is nothing in the LCSA that prohibits EPA from removing a substance from the prioritization process once it has initiated that process. Further, this is consistent with Congress's intent for EPA to be able to use Section 4 authority for prioritization purposes (if the conditions cited in the paragraph above can be met). Without this discretion to remove a substance (temporarily) from the prioritization process, the Section 6(b)(1)(C) overall timeframe of 9-12 months to make a prioritization designation, (including: the Section 6(b)(1)(C)(i) requirement for submitters to provide EPA information within 90 days of initiation of prioritization; the Section 6(b)(1)(C)(ii) requirement for a 90-day public comment period; and the three month limitation on an extension for EPA to receive or evaluate Section 4(a)(2)(B) developed information) would significantly limit Section 4's utility in prioritization since 9-15 months may not be enough time to conduct many types of scientific testing or to develop new exposure information.

In addition, because EPA is required under the Act to use a tiered approach to screening and testing under Section 4, ACC recommends that EPA include this requirement in the prioritization rule since this requirement applies equally to the testing for prioritization purposes as it does to testing for other purposes, as well as to gathering new exposure information. If EPA uses this authority to obtain information to prioritize, EPA is required to make public a statement of need, in which it identifies the need for information; how the information reasonably available to the Agency was used to inform EPA's decision that new information is necessary; explain the basis for any decision requiring the use of vertebrate animals; and why an order is necessary over a rule or consent agreement, pursuant to Section 4(a)(4).

Beyond Section 4, EPA also might consider providing advance notice about its plans to initiate the prioritization process on substances, before actually initiating the process, to allow companies more time in advance of the prioritization process to gather relevant information for prioritization. EPA could do this either directly through informal requests from EPA to specific manufacturers or indirectly by posting its preliminary plans on its website.

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[1] See for example Aylward et al., 2013 Evaluation of biomonitoring data from the CDC National Exposure Report in a risk assessment context: perspectives across chemicals Environ Health Perspect. 121:287-294; http://www.ncbi.nlm.nih.gov/pubmed/23232556

## IV. Relationship between Section 6 Prioritization Requirements and Section 8 Reporting

Section 8 requires an Inventory "reset" to distinguish between those chemicals on the Inventory that are currently active in commerce and those that are inactive, according to the specific terms set forth in the statute. This will permit EPA to focus its attention on those chemicals that are active in commerce for purposes of prioritization. EPA need not focus on any chemicals on the inactive portion of the Inventory for prioritization unless and until it receives notice of a chemical re-entering active commerce.

EPA should utilize all of the updated use and exposure information from the 2016 Chemical Data Reporting (CDR), scheduled to be completed in 2016 well before this proposed rule will be published, to inform its prioritization. Once EPA publishes its proposed priority designations for comment, EPA should consider the information it receives from stakeholders (and in particular should solicit input from processors) to refine its initial prioritization designations. While there are certainly limitations to the use and exposure information on the CDR, it is a starting place for data and information and it, along with the Toxic Release Inventory (TRI) information, will provide a preliminary picture of use and exposure. Once the CDR, TRI and all other relevant available hazard, use, and exposure information is compiled and evaluated for preliminary priority designations, EPA may then seek input from the public and other stakeholders that EPA should factor into its prioritization designations. For example, as EPA heard during the public comments at the August 10 stakeholder meeting, the prioritization process rule should make clear that a chemical that is used exclusively as an intermediate, or in closed systems, or is fully reacted during its processing at a chemical facility site, or exists in a form in products with no exposure potential, will not pose a concern for a downstream consumer use regardless of its hazard profile.

## V. Relationship between Section 6 Prioritization Requirements and Section 14 CBI Provisions

EPA will have access to confidential business information (CBI) that may be relevant to its prioritization designations. EPA should use that information as appropriate to designate a substance as high or low priority, but must continue to protect that CBI consistent with Section 14 of the Act. This includes protecting all CBI contained within material that is otherwise not CBI as provided in Section 14(b)(1). It may very well be that a fair amount of information concerning the uses and applications of chemicals is, in fact, CBI. Much of this type of CBI will likely come from processors of chemicals, although it may more likely be available to EPA during risk evaluation rather than prioritization – given that risk evaluation is expected to be the more comprehensive or refined part of the process under the Act. EPA should work with processors and stakeholders to identify ways to protect CBI from disclosure while still utilizing the information – whether that be during prioritization or risk evaluation.

## VI. Near-Term Improvements to EPA's TSCA Work Plan Methodology to Identify Priorities Under the LCSA

ACC supports some elements of EPA's Work Plan Methodology that EPA used to identify its initial 2012 priorities and its Updated 2014 Work Plan. ACC supports the integration of hazard and exposure potential in the Work Plan Methodology. The integration of hazard and exposure is essential to ensure that the prioritization process is risk-based as is required by the Act under Section 6(b)(1)(A).

ACC also supports a 2-step process in prioritization, similar to what EPA employed in its Methodology. EPA used Step 1 to identify candidates for prioritization and then in Step 2, EPA screened those candidate chemicals against specific hazard and exposure criteria to develop a range of scores on the candidates to enable designation of priorities. ACC also supports the fact that EPA used readily available hazard information and, on the exposure side, EPA used a combination of readily available indicators of use and exposure. In general, the Methodology served the Agency well to begin prioritizing existing chemicals for further evaluation.

However, ACC believes that EPA's Methodology needs some improvements in the near term in order to meet the requirements of the LCSA. ACC discusses below a number of recommendations to improve the Methodology both in the near-term and longer-term. (Longer-term improvements to the EPA Methodology are discussed below in Section VII.)

1. EPA should update its Work Plan Methodology criteria to comply with the criteria outlined in the statute for designating substances as high and low priority for risk evaluations to include the following:
    a. Potentially exposed or susceptible subpopulations;
    b. Storage near significant sources of drinking water;
    c. The conditions of use or significant changes in the conditions of use; and
    d. The volume or significant changes in the volume manufactured, imported or processed.

    Any adjustments in the Methodology criteria must also support the need to designate both high and low priorities. Congress was clear in its inclusion of low priority designations that these are substances for which EPA has sufficient information to determine that they do not meet the "may present an unreasonable risk" standard of high priority substances. Using this same standard suggests that Congress did not intend this to be an extraordinarily high hurdle, as long as EPA deems the information supporting it "sufficient." Indeed, substances designated as low priority can always be re-prioritized if and when new information comes to light that changes EPA's priority designation.

    During the August 10 stakeholder meeting on prioritization, certain commenters suggested that EPA look to the hazard traits regulation in the California's Safer Consumer Products (SCP) program as a model when crafting the LCSA prioritization process rule. ACC opposes this suggestion because the SCP program's hazard based approach and its focus on identifying chemicals in consumer products for alternatives analysis do not comport with the LCSA's criteria for designating substances as high and low priorities for risk evaluation, nor with the LCSA's approach to risk evaluation.

2. Regarding low priorities, EPA has stated publicly that it believes certain substances on its Safer Chemical Ingredient List (SCIL) could be candidates for low priority designation. ACC encourages EPA to think more broadly to identify candidates for low priority designation that have undergone risk-based prioritization screening in regulatory programs. EPA should look at those substances initially considered for inclusion in the Work Plan, but set aside based on lower scores. It should also consider substances reviewed under EPA's former programs, such as the Voluntary Children's Chemical Evaluation Program (VCCEP) and the Chemical Assessment and Management Program (ChAMP). Another important source is the 19,000 substances set

aside under the Canadian prioritization process, to the extent there is overlap of common chemicals. All of these substances from these sources should be considered as identified candidates in Step 1 of EPA's prioritization process, but all identified candidates must be screened against EPA's Step 2 criteria before designation as high or low priority.

3. EPA must update its prioritization criteria by using the "best available science" under the Act. For example, EPA's persistence and bioaccumulation (P&B) criteria used in the Work Plan Methodology are outdated. ACC recommends that EPA use a weight of evidence approach for P&B screening, taking into consideration the intrinsic properties of the substance being reviewed vs. bright line criteria. Significant advances have occurred in the understanding of P&B in the environment, starting with the Society for Environmental Toxicology and Chemistry (SETAC) Pellston Workshop for use on organic chemicals[2] and continuing with a recent historical review on the origin and evolution of P&B assessments by Matthias et al (2016)[3], which concludes:

> *"Current numerical criteria for POPs and PBTs should not be considered as unchangeable. As scientific understanding increases with better and more reliable test data and more rigorous evaluation techniques, we should reevaluate the procedures used and the numerical criteria for screening and classification of a widening range of chemical groups. WoE, as long as it is transparent, should be applied in developing these revisions. Additional higher-tier criteria, such as the TMF mentioned in REACH Annex XIII and elimination half-life (EL0.5) should be incorporated in the process of evaluation and their link to lower tiers clarified."*

The scientific study by Burkhard et al. (2011) provides additional detail on an appropriate bioaccumulation approach.[4] For persistence, higher tier information at realistic environmental concentrations should be utilized where available. Separate criteria are needed for inorganics and metals. It is especially important that the P&B criteria be upgraded in EPA's prioritization process because of the emphasis on P&B provided in the Act, e.g., the preference to make substances that have a P& B score of 3 a high priority.

4. In the near term, EPA's "list based" approach to Step 1 of its Methodology may be the only available, efficient means for EPA to complete Step 1. However, the scientific underpinnings of these lists vary greatly in quality and reliability and they should be reviewed against the best available science requirements of Section 26(h).

5. EPA should improve overall improve transparency and openness. Although EPA's Methodology describes the criteria applied, it is not fully transparent. For example, one component of the exposure score is the use type (0-3). General criteria are described, and some examples of

[2] SETAC Pellston Workshop on Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs.
[3] The Origin and Evolution of Assessment Criteria for Persistent, Bioaccumulative and Toxic (PBT) chemicals and Persistent Organic Pollutants (POPs), M. Matthies et al, Environ. Sci.: Processes Impacts, 2016, DOI 10.1039/C6EM00311G.
[4] Comparing Laboratory and Field Measured Bioaccumulation Endpoints, Burkhard et al, IEAM, Vol 8, Number 1, 2011.

products that fall into each category are provided, but the Methodology fails to include a comprehensive list of products associated with each ranking in the document. The public and stakeholders still have no idea how those criteria were applied to score the chemicals reviewed in Step 2. Section 26(j) of the LCSA now requires EPA to make available to the public with each prioritization designation that information, analysis, and basis used to make the designation.

Related to transparency is the critical need for greater openness by the Agency. ACC is encouraged by EPA's greater engagement with stakeholders upon enactment of the LCSA, but it will be critical for EPA to continue this approach. ACC suggests that EPA look to Canada's routinized engagement with stakeholders in its implementation of the Canadian Chemical Management Plan (CMP) as a model to emulate. Canadian stakeholders and regulators have a productive relationship that seems to work effectively and efficiently.

6. EPA should refresh the 2014 Work Plan based on new and improved information when it is available. For example, the 2016 CDR will be available to the Agency once reporting is completed in the fall of 2016, although ACC recognizes EPA will need some time to assess and apply the CDR information to its prioritization process.

7. For prioritization purposes, ACC supports the application of broader categories of use, such as those outlined in the CDR, as exposure considerations for "conditions of use." We also encourage EPA to allow for further granularity in prioritization based on information received from stakeholders. For example, EPA should distinguish between the intentional use of a chemical in a product and its use as a chemical intermediate during manufacturing only, where the potential for exposure may be significantly lower in the latter scenario. Another source of information available to the Agency is the OECD's harmonization of use codes project, which includes refined subcategories of uses and related exposure levels for every CDR category. Since there is not currently enough detail in the CDR to indicate more specificity regarding "use type," the prioritization process as a whole will benefit greatly if EPA seeks and obtains this type of information either before or during the public comment period on potential candidate designations and then incorporates that information into the final prioritization.

8. ACC recognizes the large and important job that the LCSA requires of EPA and we strongly encourage the Agency to continue to hold stakeholder discussions throughout the process to increase EPA's efficiency in implementing the requirements. For example, as mentioned above, EPA could use stakeholder discussions on potential candidates for prioritization to identify the type of information that EPA would find useful for prioritization purposes.

9. ACC strongly recommends that EPA communicate the prioritization results publicly in a careful and thoughtful manner – just as it did when it communicated the meaning of the identification of substances for the Work Plan. Using neutral terms, such as "candidates for priority decisions" or "high priority substances for risk evaluation," rather than terms which could be misconstrued as indicating the substances have already been determined to present unreasonable risk will be important.

## VII. Longer Term Improvements

ACC recommends that EPA move away from reliance upon established, hazard-based lists of chemicals as its starting point for prioritization. In addition to the fact that reliance on these lists likely excludes the vast majority of chemicals active in commerce from screening, these hazard-based lists create an inconsistent and unreliable starting point. Many of these lists have been developed by various non-governmental organizations for various purposes and are of variable quality and transparency.

In the longer term, ACC encourages EPA to consider a placeholder in its prioritization process to incorporate promising new methods for prioritization such as the ToxCast and Omics testing methods for assessing bioactivity on the hazard side, and High Throughput (HTP) Exposure Modeling for exposure predictions. When these tools are more fully developed and validated, they will offer an alternative to EPA's current Step 1 under the Work Plan Methodology and the Agency will be able to screen all active substances across the Inventory quickly and efficiently.

## VIII. Conclusion

In conclusion, it is ACC's position that the more certainty EPA can provide in the prioritization rule about both the substantive scientific process requirements that EPA must meet in making its prioritization designations as well as the procedures that must be followed leading up to a designation of a substance as a high or low priority f or risk evaluation, the greater the consistency in EPA's prioritization decisions over time. This in turn will ensure a science and risk -based prioritization process that will contribute to greater public confidence in EPA's over-all decision-making about chemicals under the LCSA.

## ACC's General Principles on Prioritization

(Developed for EPA Dialogue 7-2011)

- EPA should **systematically prioritize** chemicals for purposes of safe use determinations.
- As a general matter, prioritization should be based on **existing hazard and exposure data and information (including models, read across, QSAR, etc.)** and **industry should be responsible** for providing EPA with this data and information.
- Chemicals **lacking adequate hazard and exposure** information should be considered **a higher priority** (until relevant information is provided that suggests otherwise).
- Industry should be provided an **opportunity to provide EPA additional data/information.** (Timing is an issue, however. And the format in which the information is provided to EPA must be useable/digestible by EPA, e.g. robust summaries.)
- **Hazard, use and exposure based criteria should be integrated** to form the basis for EPA's prioritization decisions. Prioritization should not be based on either hazard-only or exposure-only information.
- The prioritization process and science based criteria that EPA uses to prioritize chemicals must be **transparent.**
- Prioritization should be a **dynamic, iterative process**. Re-examination of priorities should occur as new information becomes available and as new chemicals are approved for manufacturing.
- For prioritization to be successful, it must include three critical elements: **reliable and up-to-date chemical data and information; evaluation criteria that consider both hazard and exposure information together; and established cutoffs to make priority decisions.**
- **EPA's communication about priority chemicals must be clear about what the list is and what it is not, to avoid unintended consequences of product de-selection** purely on the basis of listing.
- **Transparency; consistent, scientific criteria; intersection of both hazard and exposure information; dynamic process** so new information can be incorporated as it's made available and so if priorities are initially "wrong" they can be corrected.

# ACC Prioritization Screening Approach

## I. Introduction

This document provides background on ACC's approach to chemical prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures.
- Apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Include criteria applicable to the range of chemicals being screened. Apply this principle through a two-step process rather than just those information elements available only for subsets of chemicals.
- Leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
- Incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. improvements in how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- Adopt a simple, transparent screening method.
- Include opportunity for public review and comment to ensure the best available data and information is used in prioritization decisions.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.

## II. Applying Initial Screening Step in ACC's Prioritization Approach

The first step in applying ACC's prioritization approach is to apply criteria on human health and environmental toxicity potential to chemical substances.

### A. Hazard Potential

The U.N. Globally Harmonized System of Classification and Labeling (GHS) was developed and internationally agreed to by many governments to provide criteria and a consistent approach for hazard classification of chemicals. It can also provide a recognized and generally accepted method for sorting chemicals in a prioritization process. The GHS framework has been used by international bodies, such as the OECD and WHO, and was endorsed by EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to support prioritization.

The GHS system applies to both human health and ecological endpoints. It includes criteria for both human and ecological health. For human health, criteria are available for both acute and chronic classifications, as well as CMR categorization. For ecological

endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all substances. GHS classification information is readily available for all substances, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements.

ACC's support of the GHS criteria for purposes of this prioritization tool is not a categorical endorsement of the GHS criteria for any other purpose. ACC has been an active participant in the development of GHS and supports the system in principle. The GHS has not been broadly implemented to date in the U.S., although the Occupational Safety and Health Administration (OSHA) has indicated an intent to publish a regulation applying GHS in the workplace. ACC's December 29, 2009, comments on OSHA's proposed rule to modify the existing Hazard Communication Standard (HCS) to reflect the GHS urged that implementation of the GHS adhere to certain principles (e.g., continued application of the "Building Block Approach" of the Purple Book). ACC made specific recommendations concerning details of the Hazard Classification definitions, cut-off values, among others. ACC stands behind those comments. In ACC's view, the use of GHS criteria in a screening-level prioritization of chemicals can materially assist in determining which chemicals receive additional evaluation by the Environmental Protection Agency, but does not necessarily preclude the use of other appropriate, applicable criteria developed under other systems.

To classify a chemical in a hazard based priority ranking where there is not direct data on the chemical, EPA can employ the full range of approaches, such as QSAR, SAR, read-across and other modeling tools in which EPA has confidence based on molecular structure. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical would be classified as "high" for its environmental or health ranking.

### *1. Environmental Ranking*

Table 1 provides a summary of how GHS criteria could be logically used for chemical management prioritization.

**Table 1. Environmental Safety - Hazard Ranking**

| GHS Classification - Environmental | Ranking | Environmental Rank Score |
|---|---|---|
| Acute I or Chronic I or Insufficient Information to Classify | High | 4 |
| Acute II or Chronic II | Medium High | 3 |
| Acute III or Chronic III/IV or none | Medium | 2 |
| Not classified | Low | 1 |

## 2. *Human Health Ranking*

**Table 2. Human Health - Hazard Ranking**

| GHS Classification - Human Health | Ranking | Health Rank Score |
|---|---|---|
| GHS CMR Cat 1a, 1b; OR<br>Repeat Dose </= 10 mg/kg/day (oral);<br></= 20 mg/kg/day (dermal);<br></= 50 ppm/6hr/day (gas inhalation);<br></= 0.2 mg/l/6h/day (vapour inhalation);<br></= 0.02 mg/l/6h/day (dust mist fume inhal).<br>OR insufficient information to classify | High | 4 |
| GHS CMR Cat 2; OR<br>Repeat Dose 10 - 100 mg/kg/day (oral);<br>20 - 200 mg/kg/day (dermal);<br>50 - 250 ppm/6hr/day (gas inhalation);<br>0.2 - 1.0 mg/l/6h/day (vapour inhalation);<br>0.02 - 0.2 mg/l/6h/day (dust mist fume inhal). | Medium High | 3 |
| Not carcinogen/mutagen/repro/develop;OR<br>Repeat Dose 100 - 1000 mg/kg/day (oral);<br>200 - 2000 mg/kg/day (dermal);<br>250 - 1000 ppm/6hr/day (gas inhalation);<br>1.0 - 5.0 mg/l/6h/day (vapour inhalation);<br>0.2 - 1.0 mg/l/6h/day (dust mist fume inhal). | Medium | 2 |
| Not carcinogen/mutagen/repro/develop; OR<br>Repeat Dose >1000 mg/kg/day (oral);<br>> 2000 mg/kg/day (dermal);<br>> 1000 ppm/6hr/day (gas inhalation);<br>>5.0 mg/l/6h/day (vapour inhalation);<br>> 1.0 mg/l/6h/day (dust mist fume inhal). | Low | 1 |

It is important to note that specific concerns about children's health (specifically potential hazards and adverse effects on the nervous system) and those caused by endocrine disruption mechanisms are addressed in this prioritization process:

- The GHS CMR "R" classification includes specific evaluation of effects on development in utero and upon growth, maturation and reproduction. ("R" stands for reproductive toxicity and includes adverse effects on sexual function and fertility, as well as developmental toxicity in offspring).
- Endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a compound's ability to interact with components of the endocrine system. The prioritization process evaluates data and information on relevant apical tests, including tests for reproduction and developmental toxicity (potential

effects, which can be mediated by endocrine pathways). Thus, even if specific screening for potential endocrine activity has not yet been conducted on certain compounds, hazard identification based on observable outcomes from apical toxicity tests (e.g., outcomes such as pathologic states indicative of disease conditions) covers all modes of action, including endocrine pathways.

- The toxicity information evaluated (CMR and repeat dose toxicity) is directly relevant to evaluating potential hazards to all individuals, including children. Such data typically includes: 1) identification and definition of possible hazards upon all major organ systems from both acute and repeated exposures, including the nervous system; 2) detection of potential hazards arising from in utero exposures, including possible effects on the nervous system; 3) evaluation of potential of a substance to affect reproduction; and 4) evaluation of the potential of a substance to damage DNA.

*Integration of Hazard Elements:*
Each of the environmental and human health classifications is assigned a numeric value based upon its ranking, with 1 being the lowest value and 4 the highest. The greatest ranking (highest hazard potential score) of either Environmental or Human Health is used in a substance-specific priority ranking. The numeric value does not imply relative weighting, but rather a numerical order of priority.

**B. Exposure Potential Ranking**

The screening method allows for an initial indication of the extent of exposure potential by considering:

1. The chemical's uses and use pattern(s).
2. Production volume as a first pass indicator of relative emission/release potential since magnitude and route (i.e. air, water, soil) of emissions is not available for all substances.
3. Persistence and bioaccumulation characteristics of the substance.

Together the 3 elements are used to rank exposure potential.

*1. Use Patterns*

The proposed approach applies the most current 2006 TSCA Inventory Update Reporting rule (IUR, now called the Chemical Data Reporting rule (CDR) data. To keep the initial prioritization simple and transparent, the approach "bins" different use patterns to align with general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are the same as those reported in the IUR and are consistent with REACH exposure categories (intermediates, worker, professional, consumer). Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. For the initial prioritization approach, child specific products are captured under general consumer products and all consumer products are weighted equally (see additional

discussion below under Second Tier Considerations). Intermediates will have low general population exposures, since these substances are consumed, by definition, within the workplace. Therefore, they are given the lowest priority ranking within the approach. In the context of the proposed approach, the intermediates category includes both intermediates and non-isolated intermediates. A chemical used in multiple use patterns is assigned the priority of the highest use, e.g., a chemical in both industrial and commercial uses would be assigned the commercial Medium-High rank.

**Table 3. Use Patterns - Exposure Ranking**

| Use Pattern | Ranking | Use Pattern Score |
|---|---|---|
| Consumer | High | 4 |
| Commercial | Medium-High | 3 |
| Industrial | Medium | 2 |
| Intermediates | Low | 1 |

The IUR Definitions of these terms are (40 CFR 710.3, 710.43):

- "consumer use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of article) when sold to or made available to consumers for their use.
- "commercial use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "industrial use" means use at a site at which one or more chemical substances or mixtures are manufactured (including imported).
- "intermediate" means any chemical substance:
    - which is intentionally removed from the equipment in which it is manufactured, and
    - which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)
- "non-isolated intermediate" means any intermediate that is not intentionally removed from the equipment in which is it manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

2. *Production Volume*

Recognizing that detailed exposure information will not be available for all substances to be screened, the proposed approach uses production volume as an indicator of exposure, which is widely used in many prioritization schemes. As production volume is just a rough surrogate of emissions, ACC suggests only very broad categories, covering about

two orders of magnitude each. It may be useful to consider how additional exposure estimates may be applied in the second tier assessment.

**Table 4. Production Volume as Emission Surrogate - Exposure Ranking**

| Production Volume as Emission Surrogate | Ranking | Volume Score |
|---|---|---|
| >= 100,000,000 lbs national aggregate | High | 4 |
| 1,000,000 lbs to < 100,000,000 lbs national aggregate | Medium – High | 3 |
| >= 25,000 lbs to < 1,000,000 lbs national aggregate | Medium | 2 |
| < 25,000 lbs (below IUR site reporting limit) | Low | 1 |

*3. Persistence and Bioaccumulation*

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the approach. A persistent substance that is emitted to the environment at the same rate as a non-persistent substance with similar partitioning properties will result in higher exposure to humans and the environment. In fact, multimedia modeling clearly indicates that environmental persistence in the compartment to which a substance partitions is a good indicator of human exposure potential (MacLeod & McKone et al. 2004). Similarly, substances that are not subject to biotransformation by higher organisms will exhibit a high bioaccumulation potential that results in higher exposures via the food chain (Arnot et al. 2010). Therefore, it is recommended to apply the proposed persistence and bioaccumulation criteria in assessment of exposure potential as described below.

The persistent and bioaccumulative (P&B) criteria of the proposed approach are targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals, as in the approach taken by Canada's Chemical Management Program (CMP).

For assessing persistence, based upon recent expert consensus (Boethling et al., 2009) it is recommended to distinguish persistent from non-persistent chemicals using the following criteria:

- Volatile chemicals can be defined using a vapor pressure cut-off (i.e., > 1000 Pa)
    - For volatile chemicals, persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a substance is not persistent if air half life is < 2 days).
    - For non-volatile chemicals, non-persistent substances can be defined as substances that are deemed:
        - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) or SAR or read across from measured data on a related substance,
        - show an equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111),

        - evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days, OR
        - if data are lacking, evaluation via BIOWIN model (EPIWEB 4)
    - Non-volatile substances that are not biodegradable or subject to abiotic losses based on the above criteria would be considered persistent.

For assessing bioaccumulation, the key question for screening is the potential for biomagnification based on recent expert consensus (Gobas et al. 2009). To determine if a substance has the potential to biomagnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000. These metrics can be derived using lab or field measurements (where available) or recently improved computational models that are included in EPA's EPIWEB model that can be freely downloaded at www.epa.gov/oppt/exposure/pubs/episuite.htm.

This approach allows all organics to be addressed and is a scientifically updated version of the approach used in Canada's CMP.

Based on the above recommendations, substances can be grouped with regard to persistence and bioaccumulation as follows:

**Table 5. Persistence and Bioaccumulation - Exposure Ranking**

| Persistence and Bioaccumulation | P&B Ranking | P&B Score |
|---|---|---|
| Persistent and Bioaccumulative | High | 5 |
| Persistent and Not Bioaccumulative OR Not Persistent and Bioaccumulative | Medium | 3 |
| Not Persistent and Not Bioaccumulative | Low | 1 |

*Integration of Exposure Elements:*

As demonstrated in the tables, each factor (use pattern, P&B, and production volume) would be assigned a numeric score based upon its ranking. All 3 factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential. A proposed "banding" approach is illustrated in Table 6.

**Table 6. Integration of Exposure Rankings**

| Combined Score – All 3 elements | Exposure Rank | Exposure Ranking Score |
|---|---|---|
| 11 – 13 | High | 5 |
| 9 – 10 | Medium High | 4 |
| 7 – 8 | Medium | 3 |
| 5 – 6 | Medium Low | 2 |
| 3 – 4 | Low | 1 |

**Overall Priority Grouping:**
In the overall approach, both hazard and exposure elements are considered when placing a substance in a risk-based prioritization ranking. The overall prioritization score for priority grouping and risk evaluation is based on the combined consideration of the hazard and exposure rankings. Priority Groups 7, 8, and 9 are deemed High Priority; Priority Groups 4, 5, and 6 are Medium Priority; and Priority Groups 2 and 3 are Low Priority.

**Review and Comment:**
It is important that screening be done in an open and transparent way and that the best available information be used. When screening for thousands of chemicals, EPA may not have access to all available information. The process should provide an opportunity for review and comment on initial rankings and an opportunity to submit additional relevant data and information to update proposed rankings with improved information.

## III. Second Tier Considerations:

After the initial screening, some substances within individual priority groupings may require further rank ordering, particularly where a large number of chemicals are in the same priority group. Listed below are the types of information that will be useful to consider in this Second Tier rank ordering:

**Biomonitoring/Environmental Monitoring Data:**
Mere detection of chemicals in humans or the environment, i.e.,"found in biomonitoring (CDC), found in water (NCOD), and found in air", while providing an indication of exposure, does not provide a useful criterion for exposure potential because almost any industrial or commercial chemical could be detected at trace levels, given increasingly sensitive analytical methods. Therefore, detection alone primarily reflects only the fact that a specific chemical was included in a measurement program. This criterion will also tend to bias the prioritization of chemicals for which well-established analytical methods are available. Consequently, this criterion is not used in the initial prioritization scheme. However, within a particular priority grouping, reliable monitoring information should be considered for Second Tier rank ordering within a quantitative process that assesses if the data is above a level of concern (i.e., places it in a risk context).

**Use in Children's Products:**

Protection of childrens' health is a top priority and, in the initial ranking, child-specific products are captured under general consumer products and all consumer products are weighted equally. The specific IUR reporting of information on chemical use in products intended for children would be considered further within a particular priority grouping for Second Tier rank ordering, noting the following points:

- the IUR definition is based upon use in a child specific product rather than child specific exposure potential[1] (see below). Without knowing a specific product type, it is difficult to understand if potential child exposure is greater than for a non-child specific product. For example, how does child exposure to a general use cleaner compare to exposure from use in a child's raincoat. In the VCCEP assessments, there are examples for inhalation exposures where estimates of passive child exposure during adult product use exceeded conservative estimates of child exposure during active use of a child-specific product (such as a hobby product) – differences were related to the amount of product used and substance concentration within the product (MEK VCCEP Submission).
- the IUR definition targets children age 14 and younger. Younger children may be exposed to a variety of non-child specific products that are in general household use. Older children may be exposed to a variety of additional products.
- the IUR information request is targeted to manufacturers, which may not have direct knowledge of all uses, particularly the presence in products for specific subpopulations, such as children. Therefore, it is not clear that the information requested for the IUR information would be consistently available across all substances being screened. Ideally, this information should be requested from formulators of child-specific products.

Therefore, for the initial prioritization approach, which represents a broad, unrefined categorization, child specific products are captured under general consumer products and all consumer products are weighted equally. The IUR information on child specific use would be utilized within a particular priority grouping for Second Tier rank ordering. If the IUR information is utilized, it is important that the limitations above be considered in its application.

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[1] IUR definition (Federal Register Volume 75, Number 156, Friday August 30, 2010, p. 49686): Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least on of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:
(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?
(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?
(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

**Emissions Data:**
Production volume, which is readily available for substances, is used in this proposed approach, but only serves as a surrogate for environmental emissions. For further prioritization, data or estimates of environmental emissions can be used to refine prioritization. Estimates of environmental emissions will be available for some substances (e.g., TRI data). When TRI data are utilized it should be recognized that it addresses only emissions that result from industrial and not wide dispersive uses. In other cases, emissions estimates can be developed as a percentage of production volume based upon consideration of use categories. Within a particular priority grouping, available emissions information can be considered for Second Tier rank ordering, with the understanding that emissions information is not an indicator of actual exposure.

Similarly, non-isolated system intermediates, by definition, would have de minimis exposure potential. Therefore, this IUR information could be considered within a particular priority grouping for Second Tier rank ordering.

**International Risk Management Actions:**
An initial screening approach for chemical prioritization should be based upon consistent application of specific hazard and exposure science elements that define risk potential. The hazard and exposure elements should be applicable across all substances being evaluated. For initial screening, existence of international risk management action plans should not be a factor that determines priority grouping. Risk management plans may be based upon many factors, including political drivers. It is unclear how factors, their relative weighting, and the rigor of the evaluation may vary across agencies and substances. For initial screening purposes, the same science-based criteria should be used to rank all substances. Consideration of existing international risk management plans could be utilized to check the functioning of the approach and could be considered within a particular priority grouping for Second Tier rank ordering with the possible effect of moving a chemical up in a grouping if actions are being taken internationally.

## IV. Summary

ACC's prioritization approach is an example of a risk-based screening prioritization process that implements the general principles outlined at the outset of this document. It is based upon widely available information that can be utilized to understand the relative priority of chemicals for further evaluation from a risk perspective, i.e., integrating both hazard and exposure elements. Implementation of the screening framework will be most effective when utilizing the best available information. When conducting screening for thousands of chemicals, EPA may not have access to all available information. An open and iterative process that includes an opportunity for review and comment on initial rankings, together with the information that led to the result, and an opportunity to update the ranking with improved information will create a transparent and scientifically sound process.

## V. References

Arnot, J.A., D. Mackay, T. F. Parkerton, R. T. Zaleski, C. S. Warren (2010), Multimedia modeling of human exposure to chemical substances: The roles of food web biomagnification and biotransformation, Environmental Toxicology and Chemistry 29(1):45–55.

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Gobas, F.A.P.C, W. de Wolf, L. P Burkhard, E. Verbruggen, K. Plotzke (2009). Revisiting Bioaccumulation Criteria for POPs and PBT Assessments Integrated Environmental Assessment and Management, 5(4):624–637.

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van Wijk,D., R. Chénier, T. Henry, M. D Hernando, C. Schulte (2009). Integrated Approach to PBT and POP Prioritization and Risk Assessment' Integrated Environmental Assessment and Management, 5(4):697–711.

# Proposed Prioritization Approach

DRAFT May 6, 2011

| Exposure Elements | | | | |
|---|---|---|---|---|
| Use Pattern | intermediate | industrial - not intermediate | commercial | consumer |
| Use Score | 1 | 2 | 3 | 4 |
| Persistence / Bioaccumulation (PB) | not P, not B | | P & not B OR B & not P | P&B |
| PB Score | 1 | | 3 | 5 |
| Tonnage | <25,000 lbs (below IUR site reporting limit) | 25,000 - <1MM lbs IUR aggregate | 1MM- <100MM lbs IUR aggregate | ≥ 100MM lbs IUR aggregate |
| Tonnage Score | 1 | 2 | 3 | 4 |
| **SUM (Use + PB + Tonnage Scores)** | **range 3 -13** | | | |

| PRIORITY GROUPING = Hazard + Exposure Rankings | | | | Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | 3-4 | 5-6 | 7-8 | 9-10 | 11-13 |
| | | | | low | med-low | medium | med-high | high |
| Hazard Ranking = Higher Score from Environmental and Human Health Hazards | | | | 1 | 2 | 3 | 4 | 5 |
| | | Environmental Hazard | Human Health Hazard | | | | | |
| 1 | low | not classified | Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal). | 2 | 3 | 4 | 5 | 6 |
| 2 | medium | Acute III OR Chronic III/IV ; [not acutely toxic and no chronic data] | Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal). | 3 | 4 | 5 | 6 | 7 |
| 3 | med-high | Acute II or Chronic II | GHS CMR Cat 2; OR GHS Repeat Dose Cat 2: Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal). | 4 | 5 | 6 | 7 | 8 |
| 4 | high | Acute I OR Chronic I OR Insufficient information to classify | GHS CMR Cat 1a, 1b; OR GHS Repeat Dose Cat 1: Repeat Dose </= 10 mg/kg/day (oral); </= 20 mg/kg/day (dermal); </= 50 ppm/6hr/day (gas inhalation); </= 0.2 mg/l/6h/day (vapour inhalation); </= 0.02 mg/l/6h/day (dust mist fume inhal). OR Insufficient information to classify | 5 | 6 | 7 | 8 | 9 |

# Hazard and Exposure Criteria for Prioritization Approach

**HAZARD**

**Environment and Human Health Classifications based upon GHS**

**Environmental:**

From GHS classification guidance document:

**Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment**

| Classification categories | | | |
|---|---|---|---|
| **Acute hazard** *(Note 1)* | **Long-term hazard** *(Note 2)* | | |
| | **Adequate chronic toxicity data available** | | **Adequate chronic toxicity data not available** *(Note 1)* |
| | **Non-rapidly degradable substances** *(Note 3)* | **Rapidly degradable substances** *(Note 3)* | |
| **Category: Acute 1** $L(E)C_{50} \leq 1.00$ | **Category: Chronic 1** NOEC or $EC_x \leq 0.1$ | **Category: Chronic 1** NOEC or $EC_x \leq 0.01$ | **Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$ |
| **Category: Acute 2** $1.00 < L(E)C_{50} \leq 10.0$ | **Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$ | **Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$ | **Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$ |
| **Category: Acute 3** $10.0 < L(E)C_{50} \leq 100$ | | **Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$ | **Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$ |
| | **Category: Chronic 4** *(Note 4)* Example: *(Note 5)* No acute toxicity and lack of rapid degradability and BCF $\geq$ 500 or, if absent log Kow $\geq$ 4, unless NOECs > 1 mg/l | | |

**Human Health:**

As above, based upon GHS

**EXPOSURE**

**Use Elements - based upon IUR**

intermediate consumed during industrial processing
industrial (not intermediate) - used in an industrial setting
commercial occupational use in nonindustrial setting
consumer general population residential use

**Persistence:**

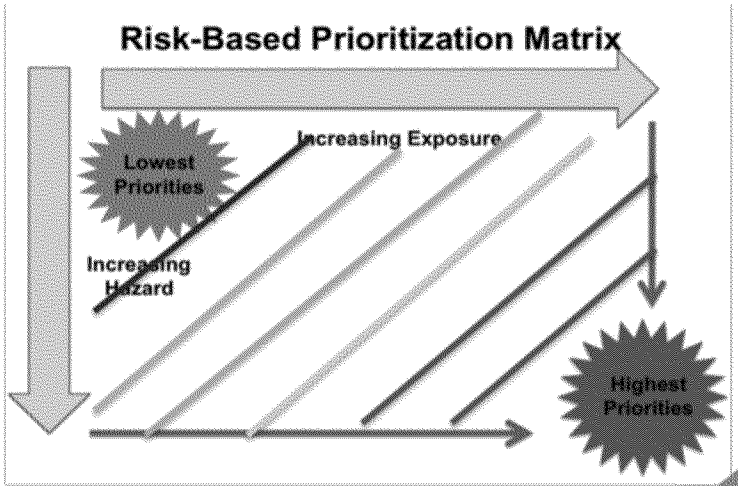
Volatile substance (VP > 1000 Pa): Not Persistent if air half life < 2 days
Nonvolatile (VP < 1000 Pa): Not Persistent if:
a) ready biodegradability (OECD 301)
b) inherent biodegradability (OECD 301, 302, 306)
c) read across from measured data on a related substance.
d) equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111)
OR, a substance is Not Persistent if:
e) evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g., OECD 308/309) have half lives below 180 days.
OR, if data are lacking:
f) evaluation via BIOWIN model (EPIWEB 4)

**Bioaccumulation:**

A substance is not bioaccumulative if:
a) measured TMF < 1 (field study)
b) measured fish BMF < 1 (lab study)
c) measured fish BCF < 5000 (lab study)
d) predicted BCF < 5000 using the BCFBAF model included in EPIWIN 4
The above order reflects the preference for use in decision-making
NOTE -- P&B CRITERIA ARE FOR ORGANICS

**Tonnage - based upon IUR reporting ranges**

< 25,000 lbs (below IUR site reporting limit)
25,000 - <1 MM lbs national aggregate
1MM - <100 MM lbs national aggregate
≥100 MM lbs national aggregate




# Two-Step Prioritization Process

## Second Tier

### Rank Ordering within Priority Groups

- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions